REMARKS

Status of the Claims

Claims 33-43 remain pending in the present application, Claims 1-32 having been previously canceled in response to a Restriction Requirement. Claims 33-36 have been amended to more clearly define the recited subject matter.

Brief Summary of Telephone Interview of January 2009

On January 8, 2009, applicant's attorney (Michael C. King; Registration No. 44,832) conducted a telephone interview to discuss the current Office Action with Examiner Timothy Maust.

The parties discussed the Klibanov reference (U.S. Patent No. 6,387,077), particularly the portions of the reference dealing with the embodiments of FIGURES 1 and 2.

A specific point of discussion was that the embodiment of FIGURE 1 rotated about a longitudinal axis of shaft 70, such that the container (reservoir 28) rotated in planetary fashion, as opposed to rotating about its own axis. Also discussed was a clutch assembly 56 that enabled the rotation and the advancement of the plunger to be decoupled, so that the planetary rotation could be implemented without also dispensing the fluid.

Another specific point of discussion was that the embodiment of FIGURE 2 rotated about a longitudinal axis of the container (syringe 23), but that the motor causing the rotation simultaneously advanced a plunger dispensing the fluid, so that rotation and dispensing had to occur at the same time.

The fifth paragraph of column 3 of the reference was discussed, in light of the structures disclosed in FIGURES 1 and 2.

The claims were then discussed, specifically that the claims required *rotating the container about its axis* and dispensing the fluid independently of the rotation of the container. Applicants pointed out that such language distinguished over FIGURE 1 of Klibanov, because in that embodiment the container rotated about a planetary orbit and not about its own axis. Applicants pointed out that such language distinguished over FIGURE 2 of Klibanov, because in that embodiment the rotation and the dispensing cannot occur independently of one another.

It became clear that emphasizing that the axis in the applicants' claims was the container's axis, not the device's axis, would facilitate distinguishing the claims over Klibanov. Applicants

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offered to prepare such an amendment, and the Examiner agreed to review such a narrowly focused amendment in light of the pending Final Rejection.

Applicants' attorney would like to thank Examiner Maust for his time and willingness to discuss this case during the Telephone Interview.

Finality of the Office Action

In the amendment submitted on August 27, 2008, applicants articulate specific reasons the pending claims distinguished over the primary reference.

The Final Office Action states that those arguments were considered, but were moot in view of new grounds of rejection and thus no further comment was made regarding the arguments.

However, the Final Office Action, while not identical to the First Office Action, does not cite any additional references, but relies on the same references cited in the First Office Action. More importantly, the logic employed in the Final Rejection is substantially similar to the logic employed in the First Office Action. The only difference applicants have identified is that the Examiner has presented the argument in the Final Office Action that removing the syringe from Klibanov's device would enable manual fluid delivery without rotation.

Applicants believe that if the Final Office Action had included an answer to applicants' traversal of the rejections presented in the First Office Action as required by MPEP 707.07(f) (the examiner should, if he or she repeats the rejection, take note of the applicants' argument and answer the substance of it), then it would have been apparent applicants' prior remarks were relevant to the statement that *removing the syringe from Klibanov's device would enable manual fluid delivery without rotation*.

Applicants traversed the initial rejection by noting that in each of the embodiments disclosed by Klibanov, the plunger cannot move (i.e., there can be no fluid delivery) unless the container is being rotated. In other words, Klibanov's principle of operation is to enable fluid delivery only while the container is being rotated (although rotation can occur without fluid delivery). Applicants further noted that applicants' principle of operation is to dispense fluid after rotation has been terminated, and that MPEP 2143.01 specifically provides that "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."

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Note that this aspect of applicants' traversal is germane to the issue raised in the Final Office Action; i.e., that *removing the syringe from Klibanov's device would enable manual fluid delivery without rotation.* Clearly, such removal represents the very type of modification to Klibanov's disclosure that would impermissibly require changing Klibanov's principle of operation, which is expressly forbidden by MPEP 2143.01.

In other words, applicants have already entered into the record the notion that MPEP 2143.01 prevents a modification to Klibanov which would result in fluid being delivered without rotation, yet such a modification appears to be the basis for the Final Office Action.

While the Examiner is certainly free to disagree with applicants' position, MPEP 707.07(f) would appear to require a subsequent Office Action to answer the substance of applicants' traversal when the same issues are present. Here, the issue of whether or not MPEP 2143.01 prevents Klibanov from being modified such that fluid is delivered in the absence of rotation (whether by removing the syringe or structurally modifying the device) is relevant to both the Final Office Action and the First Office Action, and the substance of that traversal should have been answered.

Additionally, the Final Office Action appears to repeat the same rejection of Claim 42, without answering the substance of applicants' traversal to the rejection. Particularly where an Examiner is not convinced by a traversal, entering into the record an articulation of why the rejection is being maintained expedites prosecution, by providing applicants information that can be used to determine how best to advance prosecution.

Applicants therefore respectfully request that the Finality of the present Office Action be withdrawn, should the present amendment not place the case in condition for allowance.

Claims Rejected Under 35 U.S.C. § 102(e)

Claims 33-41, and 43 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,387,077 (Klibanov et al. - hereinafter referred to as "Klibanov").

In the interest of reducing the complexity of the issues for the Examiner to consider in this response, the following discussion focuses on independent Claims 33-36.

The patentability of each remaining dependent claim is not necessarily separately addressed in detail. However, applicants' decision not to discuss the differences between the cited art and each dependent claim should not be considered as an admission that applicants concur with the Examiner's conclusion that these dependent claims are not patentable over the disclosure in the cited references.

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Similarly, applicants' decision not to discuss differences between the prior art and every claim element, or every comment made by the Examiner, should not be considered as an admission that applicants concur with the Examiner's interpretation and assertions regarding those claims. Indeed, applicants believe that all of the dependent claims patentably distinguish over the references cited. In any event, a specific traverse of the rejection of each dependent claim is not required, since dependent claims are patentable for at least the same reasons as the independent claims from which the dependent claims ultimately depend.

Discussion of Klibanov's Disclosed Embodiments

Klibanov's first embodiment is shown in FIGURE 1, and is described at column 4, line 39 to column 7, line 13. This first embodiment rotates the container in a planetary orbit about a longitudinal axis of threaded spindle 54 (see column 6, line 44). Thus, this embodiment cannot read on applicants' claims, as applicants' claims ***require*** that the container is rotated about its own axis. Furthermore, a single motor is responsible for both rotation and plunger displacement (i.e., fluid dispensing). A clutch enables the plunger to be selectively controlled, such that depending on the position of the clutch the plunger either moves or is stationary when the motor is energized. However, no clutch is provided to control the rotation of the container, thus whenever the motor is energized the container is rotating in a planetary orbit. Applicants' claims ***require*** that fluid be dispensed when the container is not rotating, and the clutch/motor configuration of Klibanov's first embodiment makes that impossible (i.e., the plunger cannot be moved without rotating the container in a planetary orbit).

Klibanov's second embodiment is shown in FIGURES 2-4, and is described at column 7, line 14 to column 9, line 2. The second or alternative embodiment of Klibanov rotates the container about its own axis (see column 8, line 42), and fluid delivery and rotation occur simultaneously (see column 8, lines 5-8 and lines 55-56). In this second embodiment, rotation and dispensing must occur at the same time because in Klibanov's second embodiment a single motor is used to move the plunger and rotate the container, and no clutch is provided to decouple those motions. The operation of the motor is described in column 8, lines 39-48, as both rotating the tumbler about the housing axis and advancing the tumbler such that the proximal portion of tumbler 108 is engaged to plunger 130 so as to advance it. In other words, the motor responsible for the plunger movement (i.e., responsible for fluid delivery) is also responsible for rotation, and thus Klibanov's second embodiment simply

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cannot dispense fluid without simultaneous rotation. When the motor stops, there is no rotation and no fluid dispensing. Thus, Klibanov's second embodiment cannot read on applicants' claims, as such claims ***require*** that dispensing occur in the absence of rotation.

Patentability of Independent Claims 33-36 over Klibanov

Based on the Telephone Interview noted above, applicants have amended Claims 33, 34, 35 and 36 to clarify that the axis of rotation referred to in the claims is a longitudinal axis of the container in which the fluid is disposed.

The claims thus require *rotating the container about its longitudinal axis* and *dispensing a fluid* ***independently*** of the rotation of a container, such that *rotation of the container is not required in order for dispensing of the fluid to occur* (Claim 35 uses slightly different wording to convey the same meaning).

The Examiner correctly notes that in one embodiment rotation can occur *before* delivery (the embodiment of FIGURE 1) and in another embodiment rotation and delivery are simultaneous (the embodiment of FIGURE 2). In both embodiments, the fluid can be delivered ***only*** while the container/syringe is being rotated (either about a device axis or the container axis).

The Examiner notes that the fluid could be delivered absent rotation if the *syringe is removed from the device*. However, Klibanov **does not** disclose delivering fluid by removing the syringe from the device, and removing the syringe from Klibanov's device represents a modification of Klibanov (thus such a medication is appropriate only in a rejection under 35 U.S.C. § 103, not 35 U.S.C. § 102). More importantly, MPEP 2143.01 notes that a proposed modification cannot render the prior art unsatisfactory for its intended purpose nor change the principle of operation of the reference. Modifying Klibanov so that the syringe is removed from the rotational apparatus would violate both those conditions.

Klibanov's devices are designed not only to rotate a syringe but also to manipulate the plunger of the syringe to deliver fluid. Those devices were clearly not intended to be used only to rotate the syringe, such that delivery of fluid occurs manually after removing the syringe from the device. In fact, the embodiment of FIGURE 2 cannot support such a use, because rotation and dispensing ***must*** occur simultaneously. While the embodiment of FIGURE 1 could be used to rotate the syringe before delivery of the fluid, Klibanov clearly teaches that the fluid is dispensed while the syringe is in the device and being rotated through a planetary orbit (if the embodiment of FIGURE 1

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was not intended to dispense fluid, plate 58 would not be necessary). Clearly, to remove the syringe for manual fluid delivery represents a step inconsistent with the intended purpose of the prior art, and changes the principle of operation of the reference, contrary to MPEP 2143.01.

Stated another way, Klibanov teaches fluid delivery while the syringe is in the device and being rotated, thus Klibanov *teaches away* from removing the syringe for manual delivery. MPEP 2145 clearly indicates that modification of a reference where the reference teaches away from the modification cannot be used as the basis for a valid rejection.

As discussed in detail above, applicants' principle of operation is to dispense fluid after rotation has been terminated. MPEP 2143.01 specifically provides that "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." Modification of Klibanov to achieve an equivalent to that which applicants have claimed would impermissibly require changing Klibanov's principle of operation. MPEP 2143.01 expressly forbids such a modification. Thus, not only does Klibanov not anticipate the claimed invention, Klibanov cannot serve as the basis for an obviousness type rejection that requires modification of Klibanov's principle of operation.

In the event that the Examiner should consider the modifications to Klibanov to achieve an equivalent invention (i.e., a method of dispensing fluid wherein a container is first rotated about its own axis for a period of time, followed by dispensing of fluid in the absence of rotation), applicants respectfully submit that the modifications required are not trivial. Significantly, in each of the two embodiments disclosed by Klibanov, the same prime mover both moves a plunger for fluid dispensing and enables the fluid container to be rotated. The first embodiment employs a clutch such that the plunger need not move when the prime mover is energized. However, the container will rotate in a planetary orbit whenever the prime mover is energized. In Klibanov's second embodiment, when the prime mover is energized both fluid dispensing and rotation occur. Significantly, in each of the embodiments disclosed by Klibanov, the plunger cannot move (i.e., there can be no fluid delivery) unless the container is being rotated. In other words, Klibanov's principle of operation is to enable fluid delivery only while the container is being rotated (although rotation can occur without fluid delivery).

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Applicants' principle of operation requires decoupling of fluid delivery with rotation. In other words, applicants' principle of operation is to dispense fluid after rotation has been terminated. MPEP 2143.01 specifically provides that "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." Modification of Klibanov to achieve an equivalent to that which applicants have claimed would impermissibly require changing Klibanov's principle of operation. MPEP 2143.01 expressly forbids such a modification.

Accordingly, the rejections of independent Claims 33, 34, 35, and 36 should be withdrawn. Because dependent claims include each element recited in the independent claim from which they depend, each claim depending on independent Claim 36 is patentable for at least the same reasons. Accordingly, the rejection of dependent Claims 37-41 and 43 should also be withdrawn.

Patentability of Independent Claim 33 over Klibanov

In addition to the amendment directed to clarifying the axis of rotation, Claim 33 has been further amended to clarify that the steps of rotation and dispensing are implemented using a device. Such language distinguishes over any modification of Klibanov to remove the syringe for manual fluid delivery. Claim 33 distinguishes over the cited art for this additional reason.

Claims Rejected Under 35 U.S.C. § 103(a)

Claim 42 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Klibanov in view of U.S. Patent No. 5,355,373 (Salmon et al. - hereinafter referred to as "Salmon").

Claim 42 recites that the frequency modulation and phase characteristics of a motor are matched to a rotation rate of the syringe to reduce pulsatility. The Examiner notes that Salmon discloses an electric motor whose frequency modulation and phase characteristics appear to be readily adjustable. Applicants respectfully submit that simply because Salmon discloses that those characteristics ***can be*** adjusted is not equivalent to teaching or suggesting that adjusting those characteristics to match a container's rotation *can reduce pulsatility*. As the Examiner has noted, Salmon's stepper motor is an improvement over prior art stepper motors because Salmon's control over frequency modulation and phase characteristics enables infinite steps to be achieved. Salmon simply does not teach that controlling frequency modulation and phase characteristics of a motor to match the rotation rate of a container will reduce pulsatility.

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In other words, while Salmon teaches that frequency modulation and phase characteristics can be used to control a stepper motor, Salmon does not teach or suggest that matching the frequency modulation and phase characteristics of a stepper motor to the rotation rate of the syringe can reduce pulsatility.

Furthermore, as noted above, Klibanov cannot serve as the basis for an obviousness type rejection that requires modification of Klibanov's principle of operation. Claim 42 requires that fluid delivery occur without rotation, and Klibanov cannot be modified to achieve such operation per MPEP 2143.01. Thus, the combination of Klibanov and Salmon cannot achieve an equivalent to that which is recited in applicants' Claim 42.

Conclusion

In consideration of the amendments to the claims and the Remarks set forth above, it is applicants' position that all claims in the current application are patentable over the art of record. The Examiner is thus requested to pass this case to issue without further delay. In the event that any other issues remain, the Examiner is invited to telephone applicants' attorney at the number listed below.

Respectfully submitted,

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